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ENVIRONMENTAL HYGIENE
AGENCY

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**HOW TO
WRITE AND MANAGE
STANDING OPERATING
PROCEDURES (SOP)**

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REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
U. S. **ARMY ENVIRONMENTAL HYGIENE AGENCY**
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USAEHA TECHNICAL GUIDE NO. 176
HOW TO WRITE AND MANAGE
STANDING OPERATING PROCEDURES (SOP)

1. Purpose

This technical guide (**TG**) is for the person who must plan, write, revise, publish, or manage **SOPs**. The guidance is presented generically so that it can be used in any setting. Examples include administrative, industrial, laboratory, or field **operations**. Therefore, this guidance addresses both the format and content of administrative and technical **SOPs**.

2. Definition

An SOP is a clearly written set of instructions or methods detailing the procedures for carrying out a routine or recurring task or study. **SOPs** are used to describe both administrative and technical tasks.

3. Use

a. As a management tool, an **SOP**—

(1) Provides a foundation for training new employees by establishing operational procedures.

(2) Serves as a continuity tool in those cases where regular personnel are absent from an operation, enabling others to carry on the function.

(3) Refreshes the memory of management and experienced employees regarding operational procedures within the organization.

(4) Helps maintain quality control by providing detailed, step-by-step guidance to personnel who are required to carry out a certain procedure.

(5) Sets forth study methods that are adequate to ensure the quality and integrity of the data generated in the course of a study.

(6) Provides a documented, historical record of an organization's operating procedures during a specific period of time.

b. As an administrative **tool**, an SOP can be used to-

- (1) Decide where in an organization a procedure should **be** carried out.
- (2) Decide what material and personnel resources are required
- (3) Outline the manner in which procedures are to be carried **out**.

4. Steps for developing and publishing an SOP

a. Review your procedures and decide what needs to **be** explained in your SOP. Seek the input of personnel who have experience in these procedures.

b. Gather information on the procedure from reference sources. Contact **other** organizations performing similar functions to see if they have an SOP. If they do, request a copy to use as a guide or source of ideas. Often, such a document can be modified to serve your needs.

c. Assemble **all** blank forms and other documents you will need to reference in the SOP*

d. Assign the SOP a number and title for identification and reference purposes.

e. Write a draft of the SOP, following the guidelines set forth in paragraph 5.

f. Review the draft SOP for technical adequacy and administrative accuracy. Make sure that the SOP conveys its message clearly, and that it answers the questions "who," "what," "when," "where," and "how."

g. Submit the draft SOP for peer review and supervisory approval.

h. Incorporate approved changes into a final version.

i. Along with your supervisor, sign and date the final version. On approval, distribute copies, as appropriate, and post a copy in the SOP file for reference (see paragraph 6).

5. Structuring your SOP

a. Format.

- (1) Figure 1 shows the suggested format for an administrative SOP.
- (2) Figure 2 shows the suggested format for a technical SOP.

b. Numbering the divisions and parts of an SOP. The divisions of an SOP (such as paragraphs, sections, and chapters) and certain parts (figures and tables) are numbered to help make referencing easier. Table 1 explains the numbering scheme.

c. Table of contents.

- (1) If the SOP is over 10 paragraphs, include a table of contents.

(2) In preparing **the** table of contents, list part, chapter, **section** and paragraph titles (if appropriate), and appendixes exactly as given in the ba~~y~~ of the text and in the same order.

d. Content.

(1) Be clear, concise, and thorough when listing the step-by-step **procedures**. Remember that the person most dependent on your SOP is the employee who may have little or no experience with the procedure in question. To better appreciate what you must communicate, place yourself in the position of the employee. Your **greatest** enemies are vagueness and imprecision. Your SOP will **be** of little use if no one can understand who is supposed to do what.

(2) Include only those steps that are carried out by the employees in the immediate organization. When **procedures** include interactions with individuals outside of the organization, indicate this but do not specify the actual steps taken by the other persons.

(3) Be comprehensive in terms of how to get the **procedure** accomplished, but do not encompass irrelevant matters.

(4) Be positive in your presentation.

e. Appendixes. Include appendixes when it is necessary to furnish additional or supplemental material (for example, reproduction of an agreement or a sample contract, list of references, sample plan for a maneuver or exercise). Appendixes, if used, are placed at the end of the document.

f. Glossary. Provide a glossary if the SOP contains more than 15 abbreviations or 5 terms.

g. Illustrations. Use illustrations only when they are essential, contribute to a clearer understanding of the subject matter, or substantially reduce the narrative portion of the SOP*.

6. Filing the SOPs

When a number of **SOPs** have accumulated in a file, incorporate them into an SOP Manual.

a. Place the individual **SOPs** into a large binder, sorting the **documents** into chapters by subject.

b. Arrange these chapters in a logical sequence (**for** example, all **administrative** procedures in one section and all laboratory procedures in another).

c. Develop a table of contents and place it in the front of the binder.

d. Place the manual alongside other references such as **ARs** and **TGs**.

7. Maintaining a historical registry for laboratory procedures

The supervisor must maintain a historical file of obsolete laboratory **SOPs** and revisions according to Title 21, Code of Federal Regulations (CFR), Section 58.81, Standard Operating Procedures, and Title 40, CFR, Section 160.8 1, Standard Operating Procedures.

a. File at least one copy of all discontinued or obsolete SOPs, perhaps in a binder stored near the SOP Manual.

b. Record the following information and attach it to the SOP cover:

This SOP was in effect for the period XX Month 19XX (original effective date) through XX Month 19XX (date SOP was removed from service). This SOP was replaced by SOP _____ (give the SOP number, effective date, and title of the new SOP).
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8. Updating the SOPs

The supervisor should review the **SOPs** at least annually to ensure the procedures remain **up-to-date** and accurately reflect changes in the work environment.

a. If no changes are necessary, the reviewing supervisor should sign and **date** a cover sheet and attach it to the file copy of the SOP. Figure 3 shows an example of a cover sheet.

b. If procedures change, rewrite the section.

(1) New material added by a change is identified by an asterisk.

(2) On rescinding a paragraph, **delete** the **body** of the paragraph but keep its number and title in its original place in the text. Mark **the** paragraph with an asterisk and write "rescinded" in parentheses after the title. The paragraph should appear in the text as follows:

*3-1. Requisitioning (Rescinded)

In any future change, keep the number, the title, and "(Rescinded)," but remove the asterisk. The number and title are not deleted until the publication is revised

(3) Prepare a memorandum to transmit the revised SOP to the user. Indicate the number of changes and the number of changed pages. Attach the memorandum to the file copy of the SOP.

c. If changes are extensive, revise the entire SOP, and follow steps addressed in paragraphs 4g through 4i.

9. Managing the SOPs

One person in your organization should-

a. Assign SOP numbers for identification purposes.

b. Know how many copies of SOPs exist for good control, management, and revision.

c. Verify that all organization SOP collections—

(1) Are updated and evaluated for currency at least annually.

(2) Contain cover sheets to show the supervisor's review (see paragraph 8).

NAME OF ORGANIZATION (e.g., Division/Branch/Office)	
(Office File Symbol)	SOP No. _____
	Disk File Name _____
	Effective Date _____
	Date Removed from Service _____
Title of SOP	
1. Purpose: A brief statement which outlines the reason for or purpose of the SOP, described in terms of function, applicability, and objective.	
2. Authority: References the regulation that calls for procedure to be performed.	
3. Abbreviations and Terms: Use a glossary if there are more than 5 terms or more than 15 abbreviations to be explained in the SOP. Otherwise, define them as they are introduced.	
4. Procedure: The main contents of the body. Procedures are an orderly series of specific actions taken to carry out an assignment. a-z. (Subheadings: use to break a procedure into major subprocedures or major components.)	
5. Safety Considerations: Include in all SOPs. If there are none, state that safety was a consideration.	
6. References: A list of other publications that are cited in the text. All such publications must be available to the user of the SOP.	

Figure 1. Sample Format for an Administrative SOP

NAME OF ORGANIZATION (e.g., Division/Branch/Office)	
Office File Symbol)	<div style="text-align: right;">SOP No, _____</div> <div style="text-align: right;">Disk File Name _____</div> <div style="text-align: right;">Effective Date _____</div> <div style="text-align: right;">Date Removed from Service _____</div>
Title of SOP	
<p>1. Purpose: A brief statement which outlines the reason for or purpose of the SOP, described in terms of function, applicability, and objective.</p> <p>2. Authority: References the regulation that calls for the procedure to be performed.</p> <p>3. Abbreviations and Terms: Use a glossary if there are more than 5 terms or more than 15 abbreviations to be explained in the SOP. Otherwise, define them as they are introduced.</p> <p>4. Restrictions: Indicates who has authority to update the SOP and when.</p> <p>5. Location: Indicates the area in which the procedures are to be followed; usually either a lab name and room number, or a field location.</p> <p>6. Scope: Describes the type of test, the nature of samples (matrix), and the type of program supported. Include linear range, level of quantitation (method detection limit), and method precision and bias.</p> <p>7. Sample Handling and Preservation: Focuses on the analyst's responsibilities in sample handling.</p> <p>8. Apparatus and Materials: Describes reagents, standards and equipment used.</p> <p>9. Analytical Procedures: Describes interferences, preparation and analysis.</p> <p>10. Quality Control: Describes the QC checks including type, frequency, evaluation procedure, acceptance and rejection criteria, and corrective actions.</p> <p>11. Data Analysis: Describes how raw data is recorded, calculations done, and results reported.</p> <p>12. Documentation: Describes the information which shall be recorded sufficient to permit validation of data.</p> <p>13. Report Requirements: Describes the information to be included in the final report.</p> <p>14. Safety Considerations: Include in all SOPs. If there are none, state that safety was a consideration.</p> <p>15. References: A list of other publications that are cited in the text. All such publications must be available to the user of the SOP.</p>	

Figure 2. Sample Format for a Technical SOP

Table 1
Numbering the divisions and parts of a publication

Division or Parts	
1. Parts	Number consecutively, spelling out the part number. For example, Part One, Part Two.
2. Chapters	Number consecutively throughout the publication , using Arabic numbers. For example, Chapter 1, Chapter 2.
3. Sections	Number consecutively within chap&s, using capital Roman numerals. For example, within Chapter 1, Section I, Section II; within Chapter 2, Section I, Section II.
4. Paragraphs ¹	Number consecutively , using two-part Arabic numbers. The first number represents the chapter; the second represents the numerical sequence of the paragraph within the chapter. For example, 1-1, 1-2; 2-1, 2-2.
5. Subparagraphs	First level: Number consecutively within each paragraph, using lower-case letters in alphabetical sequence . For example, a, b, c...z; aa, ab, ac...az; ba, bb, bc...bz. Second level: Number consecutively within each subparagraph, using Arabic numbers in parentheses . For example, within subparagraph a, (1), (2); within subparagraph b (1), (2). Third level ² : Number consecutively within each subparagraph, using lower-case letters in parentheses, in alphabetical sequence. For example, within subparagraph a(1), (a), (b); within subparagraph a(2), (a), (b).
6. Illustrations and tables	Number consecutively within each chapter, using two-part Arabic numbers. The first number represents the chapter; the second , the numerical sequence of the illustration or table within the chapter. For example, Figure 1-1, Figure 1-2, Figure 2-1, Figure 2-2; Table 1-1, Table 1-2, Table 2-1, Table 2-2.
7. Appendixes	Number consecutively, using capital letters in alphabetical sequence . For example, Appendix A, Appendix B, ³
a. Sections within an appendix	Number consecutively within each appendix as explained in Item 3 above.
b. Paragraphs within an appendix	Number consecutively , using a capital letter and an Arabic number. The letter represents the appendix; the number, the numerical sequence of the paragraph within the appendix. For example, A-1, A-2, B-1, B-2.
c. Subparagraphs within an appendix	Same as in item 5 above.
d. Illustrations and tables within an appendix	Number consecutively, using a capital letter and an Arabic number. The letter represents the appendix; the number, the numerical sequence of the illustration or table in the appendix. For example, Figure A-1, Figure A-2; Table A-1, Table A-2.
8. Glossary	Unnumbered.

¹ This item refers only to paragraphs in the body of a publication. Paragraphs in a foreword and a glossary (Item 8) are not numbered.

² A paragraph may not be divided further than the third level.

³ If there is only one appendix, call it "Appendix A."

		SOP No. _____
		Disk File Name _____
		Effective Date _____
		Date Removed from Service _____
SOP Title		
_____		_____
submitted by		Date
_____		_____
Approved by		D a t e
Reviewed		
_____		_____
Supervisor		Date
_____		_____
Supervisor		Date
_____		_____
Supervisor		Date
_____		_____
Supervisor		Date
_____		_____
Supervisor		Date
_____		_____
Supervisor		Date
_____		_____
Supervisor		Date

Figure 3. Sample of a Review Cover Sheet

